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EXAMINER	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/985,974
Filing Date: November 07, 2001
Appellant(s): BRIONI ET AL.

Gabryleda Ferrari-Dileo
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed June 19, 2006 appealing from the Office action mailed October 12, 2005.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

The following is a listing of the evidence (e.g., patents, publications, Official Notice, and admitted prior art) relied upon in the rejection of claims under appeal.

WO 99/09025	Fliri et al.	February 25, 1999
US Patent 5,883,094	Fliri et al.	March 16, 1999
US Patent 5,889,010	Faraci et al.	March 30, 1999
US Patent 5,770,606	El-Rashkly	June 23, 1998

Glass et al. 'Substituted [(4-pheylpiperazinyl)-methyl]benzamides: selective Dopamine D4 agonists," J. Med. Chem. 1997, Vol. 40, pages 1771-1772

(9) Grounds of Rejection.

1. Claims 5-6, 8, 26, 27, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fliri et al. (WO 0099/09025) and Glass et al (IDS) in view of Fliri et al. (US 5,883,094), and Faraci et al. (US 5,889,010), and in further view of El-Rashkly et al. (US patent 5,770,606).

2. Fliri et al (WO 99/09025) teaches indole derivatives, including CP-266,269, as dopamine D4 agonist. See, particularly, page 1, page 4, and pages 13-14. Glass et al. teaches that N-[[4-(2-cyanophenyl)-1-piperazinyl]methyl]-3-methyl benzamide is a known selective D4 receptor agonist, see particularly, table 1, compound 6. Fliri et al. further teaches method of using dopamine D4 receptor selective compounds for treating various dopamine related disorders. See, particularly, page 4, line 30 to page 5, line 10.

3. The primary references do not teach expressly the employment of the dopamine D4 agonists for treating sexual dysfunction.

4. However, Fliri et al. (US 5,883,094) and Faraci et al. teaches that it is known in the art that dopamine receptors are important for many functions in the animal body, such function including sexual behavior, and suggest that D4 dopamine receptor selective compounds may exert a wide range of therapeutical effect. See, particularly, column 1 in both references. Fliri et al. and Faraci et al. further teach that compounds having selective D4 dopaminergic activity are known to be useful for treating sexual dysfunction. See, particularly, column 3-5, 10-11 and the claims in Fliri et al. and column 6, line 62 to column 9, line 60, column 20, line 35 to column 22, line 55 in Faraci et al. Further, El-Rashidy et al teaches that dopamine agonists are particularly known to be useful for treating sexual dysfunction. See, particularly, the abstract, col. 3, lines 18-55.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ known D4 receptor agonists, such as those disclosed by Fliri et al.(WO 99/09025) and Glass et al. for treating sexual dysfunctions

A person of ordinary skill in the art would have been motivated to employ D4 receptor agonists, such as those disclosed by Fliri et al. (WO 99/09025) and Glass et al. for treating sexual dysfunctions because dopamine receptors are generally known to be related to sexual behavior, and, compounds having selective D4 dopaminergic activity are particularly known to be useful for treating sexual dysfunction.

(10) Response to Argument

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching,

suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the teaching, suggestion and motivation are found in the cited references and in the knowledge generally available to one of ordinary skill in the art. Particularly, the primary references teaches the compounds herein are known selective D4 receptor agonists, and are useful for treating diseases associated with D4 receptor. It is further known in the art that compounds having selective D4 dopaminergic activity are known to be useful for treating sexual dysfunction. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the claimed invention was made, to use the particular D4 agonist for treating sexual dysfunctions.

Regarding WO 99/09025, appellants contend that "the primary reference does not indicate any biological activity of the claimed compounds, leaving it to understand that these may be agonist, antagonists or have no effect at all after binding to the receptor." (page 5 of the brief). Appellants' attention is directed to page 1, lines 23-26 of '025, where it clearly states that the compounds are D-4 dopamine receptor agonists.

Appellants' attack of US patents 5,889,010 and 5,883,094 is deemed improper. Since every patent is presumed valid (35 U.S.C. 282), and since that presumption includes the presumption of operability (Metropolitan Eng. Co. v. Coe, 78 F.2d 199, 25 USPQ 216 (D.C.Cir. 1935),examiners should not express any opinion on the operability of a patent. Affidavits or declarations attacking the operability of a patent cited as a reference must rebut the presumption

of operability by a preponderance of the evidence. In re Sasse, 629 F.2d 675, 207 USPQ 107 (CCPA 1980). (MPEP 716.07).

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The examiner agrees that any one of the cited references alone would not anticipate the claimed invention. However, as discussed in the rejection, considering the cited references as a whole, one of ordinary skill in the art would have view the claimed invention as obvious.

5. Appellants' remarks about "reasonable expectation of success" are unpersuasive. Particularly, it is noted that the references have clearly suggest that D4-dopamine receptor agonist is useful for treating various disorders. Appellants suggest that since '094 teach the employment of D4 antagonist for treating sexual dysfunction, it would teaches away from the employment of D4 agonist because antagonist will have totally opposite effect in the sexual behavior of mammals. Applicants' conclusive assertion that "antagonist will have totally opposite effect in the sexual behavior of mammals" lacks factual support and are contradict to the teaching of El-Rashidy et al, and Faraci et al. (US 5,889,010), note Faraci et al. suggest that both agonist and antagonist of D4 are useful for treating dopamine associated disorders, including sexual dysfunction. See, col. 9, 55-59 and the claims. Further, Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971).

Appellants' arguments about unexpected results are not probative. Regarding the establishment of unexpected results, a few notable principles are well settled. It is applicant's burden to explain any proffered data and establish how any results therein should be taken to be unexpected and significant. See MPEP 716.02 (b). The claims must be commensurate in the scope with any evidence of unexpected results. See MPEP 716.02 (d). Further, one must compare the claimed subject matter with the closest prior art in order to be effective to rebut a prima facie case if obviousness. See, MPEP 716.02 (e). As discussed above, the prior art have suggested that compounds that selectively act on D4 dopamine receptor would exert wide range therapy, including sexual dysfunction. The evidence presented in the application shows that the selective D4 agonists have fewer side effects than apomorphine, a non-selective D dopamine receptor agonist. One of ordinary skill in the art would have not been surprised since apomorphine is not a selective D4 dopamine receptor agent.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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PRIMARY EXAMINER

SAN-MING HUI
PRIMARY EXAMINER

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